

REMARKS**I. Status of Claims**

Claims 1 and 92-98 are pending in the application. Claims 1, 93, 97 and 98 are rejected. Claims 92 and 94-96 are objected to. Claims 94-96 have been amended. Claims 2-91 were previously canceled.

Claims 94-96 have been amended to correct claim dependencies and antecedent basis.

Applicants respectfully submit that no new matter has been introduced with these amendments and therefore request entry of the amendments.

II. Claim Objections

Claims 92 and 94-96 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In view of the arguments below, Applicants respectfully submit that the objections are now moot.

III. Claim Rejection Under 35 U.S.C. 102(e)

The Examiner has rejected claims 1, 93, 97 and 98 under 35 U.S.C. 102(e) as being clearly anticipated by Moore et al. (US Patent Application Publication 2001/0021700, "Moore"). Specifically, the Examiner alleges that Moore teaches the diagnosis and treatment of immune system disorders by monitoring the expression of a gene involved in hematopoiesis, citing to paragraph 198, and further teaches assaying nucleic acids as a measurement of gene expression, citing to paragraphs 13, 15, 16, 19, and 583-589. The Examiner has noted that claims 93, 97, and 98 should have been included in this rejection in the Office action mailed April 1, 2008.

Applicants respectfully traverse the rejection and its supporting remarks. Anticipation requires that a single reference teach each and every limitation of the claim. Claim 1 is directed to a method of assessing the immune status of an individual by detecting the expression level of one or

more genes which are expressed at different levels depending on the rate of hematopoiesis or on the distribution of hematopoietic cells along their maturation pathway. Applicants assert that Moore does not teach each and every limitation of this claim.

As discussed in Applicants' response of July 1, 2008 to the previous Office action, Moore does not teach the claim limitation of assessing the immune status of an individual.

Further, Moore does not teach the claim limitation of genes that are expressed at different levels depending on the rate of hematopoiesis or on the distribution of hematopoietic cells along their maturation pathway. Instead, Moore teaches a "gene expressed primarily in ...immune cells (activated neutrophils, activated T-cells, neutrophils, and dendritic cells)" (paragraph [0195]). This gene expression pattern is different from that of the claimed invention. The gene that Moore discloses is expressed in activated neutrophils, activated T-cells, neutrophils, and dendritic cells, which are all mature cells of specific hematopoietic lineages existing in the blood, tissues, or lymph nodes after their initial differentiation and maturation in the bone marrow (see Exhibit A). In contrast, the genes of the claimed invention, those that are expressed at different levels depending on the rate of hematopoiesis or on the distribution of hematopoietic cells along their maturation pathway, are expressed dynamically in immature hematopoietic cells compared with mature hematopoietic cells. This dynamic expression pattern in which gene expression levels change depending on the maturation state of the particular hematopoietic cell is distinct from the static expression of a gene only in mature hematopoietic cells as taught in Moore.

An example of genes that are expressed at different levels depending on the rate of hematopoiesis or on the distribution of hematopoietic cells along their maturation pathway is taught in the instant specification. The genes listed in table 10 are genes and/or proteins that are expressed at high levels in immature or precursor cells of various lineages in hematopoiesis and whose expression decreases as those cells mature (page 57, 4th complete paragraph). Thus, if the rate of hematopoiesis is high and the resulting distribution of hematopoietic cells is such that there are greater numbers of immature cells compared to mature cells, the expression level of these genes will be high. If the rate of hematopoiesis is low and the resulting distribution of hematopoietic cells is

such that there are greater numbers of mature cells compared to immature cells, the expression level of these genes will be low. The sections of Moore cited by the Examiner do not teach such a gene whose expression level varies depending on the rate of hematopoiesis.

Therefore, Moore et al fails to anticipate the presently claimed invention as it does not teach each and every limitation of claim 1. Thus Applicants respectfully request that the Examiner withdraw the rejection of claim 1 under 35 U.S.C. 102(e).


IV. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **506612000104**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: April 3, 2009

Respectfully submitted,

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